

EXHIBIT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Shelby L. Cook et al.

Application No. 10/615,625

Filed: June 27, 2003

For: BIOABSORBABLE SUTURE ANCHOR
SYSTEM FOR USE IN SMALL JOINTS

Confirmation No. 9377

Art Unit: 3731

Examiner: Tuan Van Nguyen

I hereby certify that this correspondence is being sent via EFS-Web to: Mail Stop
Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-
1450, on the date shown below.

Dated: September 2, 2009

Signature: 

(Rory P. Pfeiffer)

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard
Pursuant to 37 C.F.R. § 1.131

Dear Sir:

We, Shelby L. Cook, residing at 33 Fairway Lane, Foxboro, MA 02035, Jose E. Lizardi, residing at 3 Kayla Drive, Franklin, MA 02038, Karl S. Reese, residing at 764 Tremont Street, #5 Boston, MA 02118, and Thomas A. Shepard, residing at 5250 Greens Dairy Road, Raleigh, NC 27616, hereby declare as follows:

1. As co-inventors of the subject matter claimed in this patent application, we are familiar with the patent application and its claims, as well as the development of the claimed invention. We understand that an Office Action mailed March 30, 2009, rejects claims 1, 8, 9-13, 15, 16, and 19 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7,320,701 of Haut et al. ("the Haut patent"), and furthermore, rejects claims 2, 3, 14, 17, and 18 pursuant to 35 U.S.C. §103(a) as being obvious over the Haut patent.

2. We understand that the Haut patent has a §102(e) date of June 2, 2003 (based on its filing date). We believe that the facts set forth below evidence that the invention claimed in this patent application was at least conceived prior to June 2, 2003, which is the earliest priority date that could possibly be claimed by the Haut patent.

3. Before June 2, 2003, at least two pages of drawings of the claimed invention were prepared, a redacted copy of which is attached hereto as Exhibit A. These drawings, which are dated (redacted) prior to June 2, 2003, illustrate the details of the invention as claimed in the independent claims, thus showing conception of the invention. In particular, the drawings illustrate a suture anchor for anchoring tissue to bone that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in a suture channel of the anchor. An elongate body defined by a longitudinal axis of symmetry and having a first, leading end and a second, trailing end is illustrated at least in Figures A, Sections A-A, and the perspective views of pages 1 and 2, and Figure B of page 2. Two opposed surfaces between the first and second ends and a plurality of sidewalls extending between the two opposed surfaces is illustrated at least in the Figures A and the perspective views of pages 1 and 2. Figures A and the perspective views of pages 1 and 2 also illustrate a flared portion formed on the second end and extending from one of the sidewalls. The flared portion is adapted to engage and anchor into bone tissue. A suture channel formed in the elongate body for passage of a suture strand therethrough and extending between the two opposed surfaces is illustrated at least in Section A-A of page 1 and Section A-A and Figure B of page 2. As shown, the suture channel is oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and as shown in Figures A of pages 1 and 2, a centerline of the suture channel is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion.

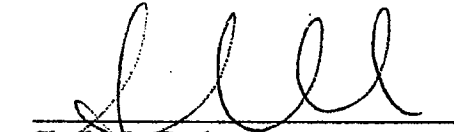
4. We were reasonably diligent in constructively reducing our invention to practice by filing a patent application on June 27, 2003, which is less than one month after the earliest priority date that could possibly be claimed by the Haut patent.

5. All of these acts relating to the conception and completion of this invention took place in the United States.

6. We further declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 14-Aug-2009


Shelby L. Cook

Date: _____

Jose E. Lizardi

Date: _____

Karl S. Reese

Date: _____

Thomas A. Shepard


1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

Date: Aug 17, 2009



Jose E. Lizardi

Date: _____

Karl S. Reese

Date: _____

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

Date: _____

Jose E. Lizardi

Date: 08/25/09

Karl S. Reese
Karl S. Reese

Date: _____

Thomas A. Shepard

1845139.1

statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Shelby L. Cook

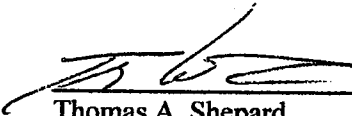
Date: _____

Jose E. Lizardi

Date: _____

Karl S. Reese

Date: 8/19/09



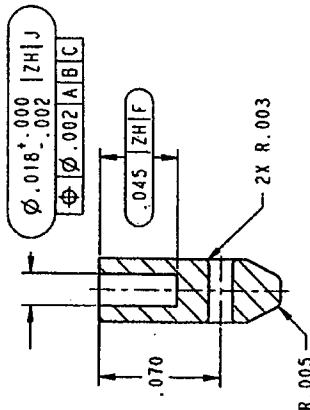
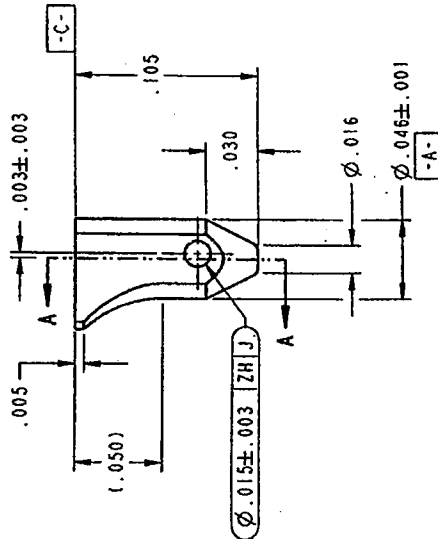
Thomas A. Shepard

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Exhibit A

DO NOT SCALE THIS DRAWING

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SECTION A-A

I. MATERIAL: REFERENCE TO P/N 105339 FOR MATERIAL SPECIFICATIONS
DYE PART #105297, D+C BLUE #6, RATIO PLA: DYE, 10,000:1
CERTIFICATION REQUIRED



3. PARTING LINE .006 MAX MISMATCH ALLOWABLE IN X AXIS. .003 MAX MISMATCH ALLOWABLE IN Y AXIS.	YB	U
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5. MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT. USE VIRGIN MATERIAL ONLY (NO REGRIND ALLOWABLE). APPLIES ONLY TO OUTSIDE SUPPLIERS.	X A	W
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005 MAY GATE VESTIGE	YB	X
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9. EFFECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE.

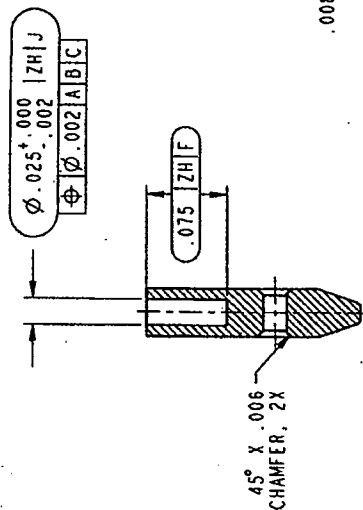
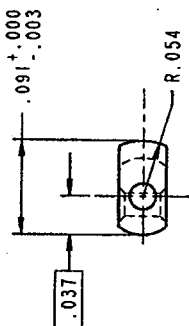
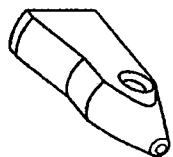
GENERAL INCOMING INSPECTION PROCEDURE.

QTY	QTY	PART OR IDENT. NO.	DESCRIPTION	ITEM NO.
1	1		ANCHOR, ABSORBABLE, MICRO (PLA)	4
				
THIRD ANGLE PROJECTION				
DIMENSIONS AND TOLERANCES				
				
TOLERANCES ON DECIMALS				
FRACTIONS 1/16 ± .005 1/8 ± .005 3/16 ± .005 1/2 ± .005 5/8 ± .005 1 ± .005 1 1/2 ± .005 2 ± .005 3 ± .005 4 ± .005 5 ± .005 6 ± .005 7 ± .005 8 ± .005 9 ± .005 10 ± .005 11 ± .005 12 ± .005 13 ± .005 14 ± .005 15 ± .005 16 ± .005 17 ± .005 18 ± .005 19 ± .005 20 ± .005 21 ± .005 22 ± .005 23 ± .005 24 ± .005 25 ± .005 26 ± .005 27 ± .005 28 ± .005 29 ± .005 30 ± .005 31 ± .005 32 ± .005 33 ± .005 34 ± .005 35 ± .005 36 ± .005 37 ± .005 38 ± .005 39 ± .005 40 ± .005 41 ± .005 42 ± .005 43 ± .005 44 ± .005 45 ± .005 46 ± .005 47 ± .005 48 ± .005 49 ± .005 50 ± .005 51 ± .005 52 ± .005 53 ± .005 54 ± .005 55 ± .005 56 ± .005 57 ± .005 58 ± .005 59 ± .005 60 ± .005 61 ± .005 62 ± .005 63 ± .005 64 ± .005 65 ± .005 66 ± .005 67 ± .005 68 ± .005 69 ± .005 70 ± .005 71 ± .005 72 ± .005 73 ± .005 74 ± .005 75 ± .005 76 ± .005 77 ± .005 78 ± .005 79 ± .005 80 ± .005 81 ± .005 82 ± .005 83 ± .005 84 ± .005 85 ± .005 86 ± .005 87 ± .005 88 ± .005 89 ± .005 90 ± .005 91 ± .005 92 ± .005 93 ± .005 94 ± .005 95 ± .005 96 ± .005 97 ± .005 98 ± .005 99 ± .005 100 ± .005 101 ± .005 102 ± .005 103 ± .005 104 ± .005 105 ± .005 106 ± .005 107 ± .005 108 ± .005 109 ± .005 110 ± .005 111 ± .005 112 ± .005 113 ± .005 114 ± .005 115 ± .005 116 ± .005 117 ± .005 118 ± .005 119 ± .005 120 ± .005 121 ± .005 122 ± .005 123 ± .005 124 ± .005 125 ± .005 126 ± .005 127 ± .005 128 ± .005 129 ± .005 130 ± .005 131 ± .005 132 ± .005 133 ± .005 134 ± .005 135 ± .005 136 ± .005 137 ± .005 138 ± .005 139 ± .005 140 ± .005 141 ± .005 142 ± .005 143 ± .005 144 ± .005 145 ± .005 146 ± .005 147 ± .005 148 ± .005 149 ± .005 150 ± .005 151 ± .005 152 ± .005 153 ± .005 154 ± .005 155 ± .005 156 ± .005 157 ± .005 158 ± .005 159 ± .005 160 ± .005 161 ± .005 162 ± .005 163 ± .005 164 ± .005 165 ± .005 166 ± .005 167 ± .005 168 ± .005 169 ± .005 170 ± .005 171 ± .005 172 ± .005 173 ± .005 174 ± .005 175 ± .005 176 ± .005 177 ± .005 178 ± .005 179 ± .005 180 ± .005 181 ± .005 182 ± .005 183 ± .005 184 ± .005 185 ± .005 186 ± .005 187 ± .005 188 ± .005 189 ± .005 190 ± .005 191 ± .005 192 ± .005 193 ± .005 194 ± .005 195 ± .005 196 ± .005 197 ± .005 198 ± .005 199 ± .005 200 ± .005 201 ± .005 202 ± .005 203 ± .005 204 ± .005 205 ± .005 206 ± .005 207 ± .005 208 ± .005 209 ± .005 210 ± .005 211 ± .005 212 ± .005 213 ± .005 214 ± .005 215 ± .005 216 ± .005 217 ± .005 218 ± .005 219 ± .005 220 ± .005 221 ± .005 222 ± .005 223 ± .005 224 ± .005 225 ± .005 226 ± .005 227 ± .005 228 ± .005 229 ± .005 230 ± .005 231 ± .005 232 ± .005 233 ± .005 234 ± .005 235 ± .005 236 ± .005 237 ± .005 238 ± .005 239 ± .005 240 ± .005 241 ± .005 242 ± .005 243 ± .005 244 ± .005 245 ± .005 246 ± .005 247 ± .005 248 ± .005 249 ± .005 250 ± .005 251 ± .005 252 ± .005 253 ± .005 254 ± .005 255 ± .005 256 ± .005 257 ± .005 258 ± .005 259 ± .005 260 ± .005 261 ± .005 262 ± .005 263 ± .005 264 ± .005 265 ± .005 266 ± .005 267 ± .005 268 ± .005 269 ± .005 270 ± .005 271 ± .005 272 ± .005 273 ± .005 274 ± .005 275 ± .005 276 ± .005 277 ± .005 278 ± .005 279 ± .005 280 ± .005 281 ± .005 282 ± .005 283 ± .005 284 ± .005 285 ± .005 286 ± .005 287 ± .005 288 ± .005 289 ± .005 290 ± .005 291 ± .005 292 ± .005 293 ± .00				

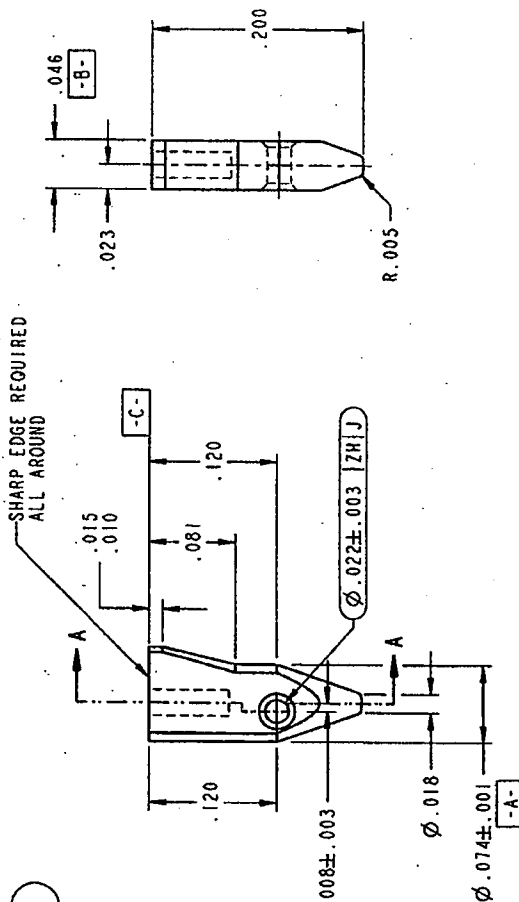
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	NEXT ASSY CATALOG NO.
	APPLICATION

REVISION

REVISION				REV	DESCRIPTION	RSD APPR	DATE	APPR	DATE
3		ADDED ROW FOR IMPROVED NOTE 7.8 & ADDED WAS .010" AND NOTE 9.0115 WAS .004			DHB			PMD	
4		.007 ± .003 - .000 WAS .003 REMOVED .008 FLAT ADDED SHARP EDGE NOTE 45° X .006 CHAMFER, 2X WAS 2X R.008			DHB			PMD	
5		ADDED .015/ .010 STEP ADDED R.011 REF. DIMENSION CORRECTED POSITION TOLERANCE			SC			LB	
6		.037 WAS .033, .081 WAS .087 .014 WAS .065, .081 WAS .065			SC			LB	
7		.008 ± .003 WAS .003 ± .002, .120 WAS .110			SC			PMD	



SECTION A-A



NOTES:

- | | |
|-----|---|
| 1. | MATERIAL: REFERENCE TO PIN 195339 FOR MATERIAL SPECIFICATIONS DYE PART # 106297, DYE BLUE #6, RATIO PLA: DYE, 10,000:1. |
| 2. | FINISH: SPE/SPI #2 (REF.). |
| 3. | PARTING LINE: .006 MAX MISMATCH ALLOWABLE IN X AXIS. .003 MAX MISMATCH ALLOWABLE IN Y AXIS. |
| 4. | PART TO BE FREE OF TOOL MARKS, SINKS, DIRT, FOREIGN MATTER AND HOLD RELEASE. |
| 5. | MATERIAL CERTIFICATION TO ACCOMPANY EACH LOT. USE VIRGIN MATERIAL ONLY (NO REGRIND ALLOWED). APPLIES ONLY TO OUTSIDE SUPPLIERS. |
| 6. | PARTS TO BE PACKAGED CLEAN, IN POLY BAGS. |
| 7. | .005 MAX GATE VESTIGE. |
| 8. | .005 MAX ALLOWABLE FLASH. |
| 9. | EJECTOR PIN MARKS TO BE FLUSH TO .0015 BELOW SURFACE. |
| 10. | INSPECT TO THE REQUIREMENTS OF SOP 2010B5, GENERAL INCOMING INSPECTION PROCEDURE. |

[illegible]